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No. 84-1529 (19)

IN THE

Supreme Court of the United States

OCTOBER TERM, 1985

MARGARET M. HECKLER, SECRETARY OF HEALTH AND HUMAN SERVICES,
Petitioner,

v.

AMERICAN HOSPITAL ASSOCIATION, *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Second Circuit

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BRIEF FOR THE RESPONDENTS THE AMERICAN MEDICAL ASSOCIATION, THE AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, THE ASSOCIATION OF AMERICAN MEDICAL COLLEGES, AND THE AMERICAN ACADEMY OF FAMILY PHYSICIANS, *ET AL.*

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QUESTIONS PRESENTED

When it enacted Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. § 794, did Congress authorize the Secretary of the Department of Health and Human Services:

(a) to investigate and regulate directly whether parents have made reasonable treatment decisions on behalf of their impaired newborn children;

(b) to supplant state officials by investigating and determining directly whether physicians have violated their state law duty under state child abuse and neglect statutes to report to state authorities known or suspected instances of parental "neglect;" and

(c) to investigate and regulate directly whether physicians' treatment decisions involving severely impaired newborn infants are appropriate under federal "504" standards of medical care which the Secretary will establish in individual cases?

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BRIEF FOR THE RESPONDENTS AMERICAN MEDICAL ASSOCIATION, *ET AL.*

INTRODUCTION

This case presents the question of whether Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. § 794, authorizes direct federal investigation and regulation of individual treatment decisions made by parents and health care providers relating to severely impaired newborn infants. The question of what sort of medical treatment, if any, should be given to severely impaired newborns is "one of the most difficult and sensitive medical and ethical problems facing our society" and federal "intervention into the difficult medical and human decisions that must be made in the delivery rooms and newborn intensive care units of our hospitals involves a *profound change* in the manner in which these decisions . . . are made." [1]

[1] *American Academy of Pediatrics* v. *Heckler*, 561 F. Supp. 395, 396, 403 (D.D.C. 1983) (Gesell, J.) (emphasis supplied).

Neither the 1973 statute nor its legislative history mentions, much less authorizes, a direct federal role in these sensitive decisions in which the infant's interests have historically been protected within the state law framework governing parent-child and physician-patient relationships. Nonetheless, until enjoined by the courts below, petitioner, the Secretary of the Department of Health and Human Services ("HHS"), had undertaken direct, intrusive and overbearing federal investigations—including 17 on-site inquiries by federal "Baby Doe" squads—in the days, even hours, immediately following the birth of a child, during a period of maximum stress for families. The focus of these HHS investigations has not been on discrimination between handicapped and non-handicapped but rather on alleged "medical neglect" of an impaired infant when its parents refuse to authorize treatment—a subject historically regulated exclusively under state child abuse and neglect laws. In not one of those 49 harmful federal investigations reported in HHS's Final Regulation on this subject (J.A. 11) did HHS find any violation of Section 504. (J.A. 96-106).

Respondents American Medical Association ("AMA") *et al.*[2] seek affirmance of the judgment below which enjoined HHS (a) from implementing the Final Regulation with respect to individual treatment decisions by parents and health care providers *and* (b) from investigating such decisions in the absence of a specific regulation on the subject, as HHS had done in all 49 of its reported inquiries. When parents *do not* consent to treatment for their seriously ill infant, HHS may not convert state law issues of possible child neglect into federal issues of discrimination against the handicapped in order to put pressure on parents through direct federal investigations, as

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[2] This case, *American Medical Association, et al.* v. *Heckler*, was brought separately and then consolidated in the District Court with *American Hospital Association, et al.* v. *Heckler* after the Court of Appeals decision in *United States* v. *University Hospital*, 729 F.2d 144 (2d Cir. 1984) (Pet. App. 4a). Respondents in each case are briefing and arguing separately in this Court.

it has tried to do in the regulatory regime invalidated below. As the Court of Appeals held, HHS has no authority to investigate and regulate directly either parental treatment decisions or physicians' duties under state law to report possible parental neglect to state authorities.

When parents *do* consent to treatment for their severely ill infant, physicians provide it. HHS has not cited, and cannot cite, even a single example when physicians have failed to provide treatment to impaired newborns after parental consent. HHS may not use this wholly implausible and highly misleading hypothetical example—which has not been the focus of its regulatory efforts, but which it emphasizes in this Court—to retain its power to conduct intrusive investigations in neonatal intensive care units.

STATEMENT

The Secretary's statement of the case (HHS Br. 2-11) is either inaccurate or incomplete in virtually every important respect. It largely ignores the medical, ethical and state law framework which is crucial to understanding this action. It also gives a completely distorted view of HHS's efforts to date by omitting *any* discussion of HHS's numerous investigations of parental decisionmaking, including its oppressive actions in the controlling *University Hospital* case.

(1) *The State Law Framework.* State law provides protection to impaired newborns when parents do not consent to treatment on their behalf. Under the law of all 50 states, parents, as the individuals best suited to protect their child, have the ultimate responsibility for making decisions about treatment for seriously ill newborns. Their decision is final except in the most extreme case when a state court has determined that a decision by the parents not to authorize treatment constitutes "medical neglect" of a child. 50 Fed. Reg. 14880 (1985). All 50 states also have child protective service agencies which are responsible for investigating reports of child abuse and neglect by parents—including "medical neglect"—and addressing the sensitive issue of when government should

institute court actions to remove the parents as decision-makers for the child. *Id.* at 14878.[3] In addition, all 50 states have mandatory statutory provisions requiring physicians to report known or suspected instances of medical neglect by parents to state authorities. Civil sanctions, criminal penalties or both may be imposed on physicians for failing to discharge these state reporting duties.[4]

State law also protects minor patients in their relationship with physicians when parents do consent to treatment. Of course, without parental consent, a physician may not treat a minor patient because treatment without such consent is a battery. *See* note 23, *infra*. But, it is a fundamental rule of state law and medical ethics that, once parental consent to treatment has been given, then physicians have a legal duty to provide appropriate medical care until the physician-patient relationship is terminated by giving the parents due notice and an opportunity to obtain other care. Under the state law doctrine of patient abandonment, if physicians withdraw before these conditions are satisfied, then they are liable for damages and subject to state disciplinary action.[5]

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[3] *See generally* Goldstein, *Medical Care for the Child at Risk: On State Supervention of Parental Autonomy*, 86 YALE L.J. 645 (1977); Wald, *State Intervention on Behalf of "Neglected" Children: A Search for Realistic Standards*, 27 STAN. L. REV. 985 (1975).

[4] *See generally* Besharov, *The Legal Aspects of Reporting Known and Suspected Child Abuse and Neglect*, 23 VILL. L. REV. 458 (1977-1978). Only physicians, not hospitals, are authorized under state law to provide medical treatment. *See* AMA & AHA, *Report of the Joint Task Force on Hospital-Medical Staff Relationships* (1985). For purposes of discussion, however, we will assume that, under the Final Regulation, the duties of physicians and hospitals (which are customarily the recipients of federal health care funds) are synonymous. *See* 49 Fed. Reg. 1637 (1984) (J.A. 65).

[5] *See* 1 D. Louisell & H. Williams, MEDICAL MALPRACTICE ¶¶ 4.12, 8.08 (rev. ed. 1984). *See also* AMA, CURRENT OPINIONS OF THE JUDICIAL COUNCIL § 8.10 (1984) (similar duty under canons of medical ethics). Medical licensing statutes also provide sanctions, including revocation or suspension of a license, for patient abandonment. *See, e.g.*, CAL. BUS. & PROF. CODE § 2234 (West Supp. 1985); D.C. CODE ANN. § 2-1326 (1981); ILL. REV. STAT. ch. 111,

(2) *The Medical and Ethical Context.* As a 1983 Presidential commission reported, the birth of an infant with severe mental or physical impairments is often an unexpected and traumatic event for parents, who are confronted with the necessity of making difficult life or death treatment decisions with little or no advance warning. In such circumstances, treatment itself may cause the infant great pain and suffering.[6] These trying cases may test the limits of medical science and present physicians with highly complex and often uncertain choices about what treatment, if any, is appropriate to recommend. Although physicians can in some cases predict with a relative degree of confidence that a particular course of treatment is likely to be beneficial or futile, there is a significant area of uncertainty (exacerbated by rapid and continuing advances in medical techniques) in which the results and consequences of a given course of treatment are simply unpredictable and may, in fact, change as the condition of the severely impaired newborn changes. *President's Commission Report* at 198, 217. Three types of medical conditions have been the subject of the most widespread medical and ethical discussion about areas of certainty and uncertainty: spina bifida, Down's Syndrome, and low birth-weight or premature infants.[7] As the *President's Commission Report* noted (at p. 220):

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§ 4433 (Smith-Hurd Supp. 1984-85); N.Y. EDUC. LAW § 6509 (McKinney Supp. 1984).

[6] *See* President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, DECIDING TO FOREGO LIFE-SUSTAINING TREATMENT 215-216 (1983) (*"President's Commission Report"*); R. Stinson and P. Stinson, THE LONG DYING OF BABY ANDREW (1983).

[7] Spina bifida with meningomyelocele is a congenital disorder characterized by an open spinal column and exposure of neural tissue and, in most cases, hydrocephalus (an abnormally large fluid collection in the brain), which can cause varying (and unpredictable) degrees of impairments, including mental retardation and paralysis. Down's Syndrome is a rare chromosomal disorder involving varying degrees of mental retardation and an increased incidence of sometimes correctable congenital defects. Premature

> Much of the difficulty in these [ambiguous] cases arises from factual uncertainty. For the many infants born prematurely, and sometimes for those with serious congenital defects, the only certainty is that without intensive care they are unlikely to survive; very little is known about how each individual will fare with treatment. Neonatology is too new a field to allow accurate predictions of which babies will survive and of the complications, handicaps, and potentials that the survivors might have. (Footnote omitted).

Nonetheless, despite this uncertainty in some cases, physicians are required by basic principles of medical ethics to provide all available medical treatment which is expected to benefit these severely impaired infants and to which parents consent.[8]

To address the difficult medical and ethical issues which can be raised by the birth of a severely impaired child, the *President's Commission Report* (at pp. 225-227; J.A. 189-192), repudiated a direct federal role like the one advanced by the Secretary and, instead, recommended the voluntary formation of infant care review committees to deal directly with the fundamental problem in this sensitive area: parental lack of information

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or low birth-weight infants, by far the largest category of cases involving difficult decisions about treatment of newborns, often suffer from a host of different but related disorders, many of them life-threatening. *See* A. Rudolph, Pediatrics 140-148, 243-245, 1594-1596 (17th ed. 1982); W. Nelson, R. Behrman & V. Vaughan, Textbook of Pediatrics 134-136, 342-353, 1561-1562 (12th ed. 1983).

[8] The AMA and other medical organizations have made clear that medical treatment which is expected to benefit the infant should always be provided and that, in determining what treatment will benefit the infant, the anticipated burdens of an impaired child on the family and on society should not be the basis for decision. *See, e.g.*, AMA, CURRENT OPINIONS OF THE JUDICIAL COUNCIL § 2.14 (1984); 49 Fed. Reg. 1622 (1984) (J.A. 12-13) (quoting *Principles of Treatment of Disabled Infants* adopted by several major medical and disability groups).

and perspective. *Id.* at 227.[9] Despite the trying circumstances in which choices must be made, parents have been able to make appropriate treatment decisions that are in the best interests of their child. *Id.* at 209 & n.51 ("rare" for parents not to act appropriately).

(3) *HHS's Intrusive Regulatory Regime: Parents As Targets.* HHS's brief mischaracterizes its regulatory pronouncements, ignores its intrusive investigative efforts and fails to describe any "problem" involving individual treatment decisions for impaired newborns which justifies a direct, intrusive federal role.

a. *HHS's Regulatory Pronouncements.* The regulatory approach reflected in the Final Regulation is the product of several rounds of official notices and interim or proposed rules published by HHS since 1982. These pronouncements reveal inconsistent and contradictory interpretations of Section 504 with respect to the three types of decisions by parents or health care providers which are at issue in this case. This regulatory history shows that the central focus of the Secretary's regulatory activities, despite contrary assertions to this Court, has been the *decision of parents not to authorize certain treatment* for their impaired newborns. The Secretary's attempt to investigate the state law *duties of health care providers to report* known or suspected instances of parental neglect was only conceived *after* the Secretary was forced to acknowledge that parental decisions not authorizing treatment could not be regulated under Section 504. Until its brief to this Court, *"non-treatment" decisions by health care providers themselves,*

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[9] *See President's Commission Report* at 227-228 (J.A. 191-192). Medical groups have made similar proposals. *See e.g.*, AMA, Judicial Council Report, *Guidelines for Ethics Committees in Health Care Institutions*, 253 J.A.M.A. 2698 (1985). These committees may be comprised of physicians, nurses, ethicists, clergy, social workers, lawyers and representatives of disability groups. At present, many hospitals with intensive care units for neonates have special review processes, including infant care review committees, for these difficult cases. 50 Fed. Reg. 14887 (1985).

when parents have given consent, have not been of any concern to HHS because such decisions never occur: HHS has never cited an instance when parents have consented to medically indicated treatment and physicians have not then provided it.

i. *The 1982 Notice.* On May 18, 1982, the Secretary issued a "notice" to health care providers stating that Section 504 applied to treatment decisions involving severely impaired newborns. 47 Fed. Reg. 26027 (1982) (J.A. 127). The Notice was clearly aimed at parents' decisions not to authorize treatment because it was explicitly addressed to the widely publicized "Baby Doe of Indiana" case, where parents had withheld consent to life-sustaining surgery and the hospital had promptly referred the matter to the appropriate state agency and courts for decision under the state's child neglect laws.[10] In this 1982 Notice, the Secretary further stated that, in cases where parents refused to authorize medically indicated treatment for their impaired newborn child, Section 504 required hospitals *to discharge the infant from the hospital* so as not to acquiesce in the parents' "discriminatory" decision.[11] The Notice made no mention of a provider's duty under state law to report instances of parental neglect to state authorities nor was there any

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[10] *See* HHS Br. 2 & n.1. In that case, the parents of a newborn with Down's Syndrome refused to authorize surgery to repair a blocked esophagus. The case was nonetheless referred to the hospital, which sought immediate judicial review. The state court decided that the parents had made a reasonable decision among treatment options. *See* 49 Fed. Reg. 1630 (1984) (J.A. 39) (comments of state court judge who decided case). The county prosecutor then brought a second action and a second state court judge also refused to find parental neglect. The infant then died. *See In re Infant Doe*, No. GU 8204-004A (April 12, 1982), *writ of mandamus dismissed sub nom. State ex rel. Infant Doe* v. *Baker*, No. 482 S 140 (Ind. May 27, 1982); J. Lyon, PLAYING GOD IN THE NURSERY 21-39 (1985).

[11] This position was roundly criticized. *See, e.g.*, Fost, *Baby Doe and Federal Funding: Putting Hospitals on Notice*, 12 HASTINGS CENTER REPORT 5, 7 (1982) (implementation of such a practice would be "gruesome").

hint that it was addressed to the situation in which physicians or hospitals refuse to provide treatment to which the parents had consented.

ii. *Interim Final Rule of 1983.* Less than one year later, HHS issued an "interim final rule" which was again aimed at *parents'* decisions not to consent to treatment on behalf of their newborn children. 48 Fed. Reg. 9630 (1983). The Interim Rule did not suggest that providers are required under Section 504 to refer cases of alleged parental medical neglect to state authorities. Instead, the Interim Rule, in complete disregard of controlling law in all states, required physicians and hospitals to provide needed medical treatment to impaired newborns regardless of the parents' treatment decision. *Id.*[12] On April 14, 1983, a district court declared the Interim Rule invalid under the Administrative Procedure Act (5 U.S.C. §§ 551 *et seq.*) because it had been issued without proper notice and comment procedures, and because HHS had arbitrarily and capriciously failed to consider "many highly relevant factors." [13]

iii. *The Final Regulation of 1984.* Following the invalidation of the Interim Rule, the Secretary on July 5, 1983, proposed a new rule, 48 Fed. Reg. 30846 (1983), which she adopted in final form with minor changes on January 12, 1984, 49 Fed. Reg. 1622 (1984) (J.A. 11) (the "Final Regulation"). The Final Regulation con-

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[12] *See American Academy of Pediatrics, supra,* 561 F. Supp. at 401 (statements of HHS counsel at oral argument) (quoted at Pet. App. 23a). There was also no suggestion that hospitals or physicians were not providing medically indicated treatment to impaired infants after parents had consented to such treatment.

[13] *American Academy of Pediatrics, supra,* 561 F. Supp. at 399. Among the many critical factors ignored or inadequately considered by HHS were: the disruptive effects on ongoing treatment of newborns caused by "the sudden descent of [federal] 'Baby Doe' squads on the scene"; the problems of ignoring parental choices about a child's "best interests"; and the fact that the administrative record failed to disclose "a widespread denial of proper newborn care such as would justify the type of regulation selected." 561 F. Supp. at 399-400.

tains four mandatory provisions: (i) each recipient hospital must post a notice with a 24-hour, toll-free "hotline" number for callers to use in reporting to HHS suspected violations of Section 504 relating to newborns; (ii) expedited HHS access to medical records is authorized; and (iii) expedited compliance actions, including referral of cases to the Justice Department, is authorized. 45 C.F.R. §§ 84.55(b), (d), (e) (J.A. 112-116). The last mandatory provision (iv) authorizes HHS to investigate directly whether hospitals and physicians are discharging their state law duty to report instances of parental neglect to state authorities. *See* 45 C.F.R. § 84.55(c) (J.A. 114-115) and pp. 25-27, *infra*.

When issuing the Final Regulation, HHS made a major, explicit concession and announced an entirely new theory of the applicability of Section 504 to treatment of impaired newborns. Contrary to the position espoused only months before in the Interim Rule, HHS in the preambles to both the proposed and Final Regulation at last explicitly conceded that, absent a state court order, only parents are authorized to make the ultimate treatment decisions on behalf of impaired newborns and that these parental decisions not to consent to treatment, no matter how "discriminatory," are outside the scope of Section 504. 48 Fed. Reg. 30848 (1983); 49 Fed. Reg. 1631 (1984) (J.A. 43-44). Nonetheless, despite this fundamental concession, the Final Regulation was still by its terms aimed at parents. *See* pp. 23-24, *infra*.

The Secretary also articulated a new Section 504 theory that, when parents withhold consent to treatment, HHS may investigate whether health care providers have discharged their duties to report cases of parental neglect to the appropriate state authorities, as required by state law. 48 Fed. Reg. 30848 (1983); 49 Fed. Reg. 1631, 1653 (1984) (J.A. 44, 122). The Secretary formally abandoned her previous Section 504 theory that, when parents did consent, providers had to treat the infant over the parents' objection or to discharge the infant from the hospital. The hypothetical issue which the Secretary em-

phasizes almost exclusively in this Court—whether Section 504 applies to "non-treatment" decisions by health care providers after parents have consented to such treatment—was not addressed in the Final Regulation nor in the supporting HHS statements.

b. *HHS's Actual Investigations.* In the preamble to the Final Regulation, the Secretary described the results of 49 separate cases in which, *without authorization by a specific regulation relating to impaired infants*, she investigated reports of suspected violations of Section 504 in the treatment of impaired newborns. 49 Fed. Reg. 1646-1649 (1984) (J.A. 96-106).[14] Not one of these cases has resulted in a finding of discriminatory withholding of medical care. Virtually all of these direct federal investigations—which were conducted within days, even hours, of the birth of the child—were aimed at decisionmaking *by parents.* In not one of these reported investigations did HHS investigate, much less find, that physicians had failed to refer cases of suspected medical neglect to state authorities. Nor was there even a hint that a physician or hospital had refused to provide a newborn infant treatment to which the parents had consented.

The futility of the Secretary's intrusive investigations, however, was not for want of trying. Of the 49 cases, fully 17 involved on-site investigations. Moreover, in over three quarters of these on-site investigations, HHS apparently made no use of qualified medical consultants, and so HHS employees, as opposed to medical experts, purported to judge the reasonableness of the complex treatment decisions at issue. Significantly, in only four

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[14] Because the Interim Rule of March 1983 had been struck down almost immediately and the proposed rule of July 1983 had no operative effect, virtually all these investigations were undertaken pursuant to the Secretary's claimed inherent authority under Section 504 and the general Section 504 regulation of 1977, 42 Fed. Reg. 22676 (1977), and not pursuant to a specific regulation relating to severely impaired infants. *See* HHS Br. 3, 44 (HHS claims inherent authority under Section 504 and general 1977 regulation to act in absence of specific regulation on impaired infants).

of the cases is there even any mention of coordination with the relevant state child protective service agency, which the Secretary has claimed she will work with closely. HHS Br. 7.[15]

HHS's own record of investigatory and enforcement activity also reveals, on its face, the significant harms that its regulatory approach has caused parents, impaired newborn infants and health care providers. *See* 49 Fed. Reg. 1632 (1984) (J.A. 47-48) (HHS's description of asserted harms of investigations and failure to show those harms do not occur). Often prompted by nothing more than anonymous telephone "tips," HHS "Baby Doe squads" descended on hospitals at all hours of the day and night, demanding to see confidential patient records, interrogating nurses, physicians and other hospital staff and, in some cases, asserting the right to examine the physical condition of the involved newborn infant.[16] As the facts of *University Hospital* illustrate graphically, *see* pp. 21-22, *infra*, the Secretary's investigatory actions had a devastating impact on the parents of the child being investigated, by subjecting them to harassing challenges to their fitness to act as decisionmakers for their child, threatening them with potential criminal liability, and embroiling them in unwanted and damaging publicity, all at a time of great emotional anguish and pressure.

Moreover, as a direct result of these investigations, critical ongoing treatment of impaired newborn infants was significantly delayed or disrupted as HHS investiga-

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[15] The preamble and interpretative guidelines to the Final Regulation provide general HHS policy on the conduct of investigations. *See* 49 Fed. Reg. 1633 (J.A. 48) (any doubts to be resolved in favor of on-site HHS investigation); *id.* 1634 (J.A. 52) (no commitment to have medical consultants present in such investigations); *id.* 1654 (J.A. 124) (HHS must itself investigate all complaints within 24 hours).

[16] *See, e.g.*, J. Lyon, PLAYING GOD IN THE NURSERY 42-44 (1985); *American Academy of Pediatrics, supra*, 561 F. Supp. at 399-400; Strain, *The American Academy of Pediatrics Comments on the "Baby Doe II" Regulations*, 309 NEW ENG. J. MED. 443 (1983).

tors monopolized patient charts and records and diverted the medical staff from its important health care functions.[17] This drain on hospital resources impaired the delivery of care to all patients and aroused unnecessary confusion, anxiety and fear among other parents and their families.[18]

(4) *The Decisions Below.* a. *University Hospital.* In November, 1983, *after* the state courts of New York had refused to intervene and *after* the state child protective service agency had determined there was no medical neglect by the parents, HHS and the Department of Justice nonetheless prosecuted a suit against University Hospital asserting, under Section 504, the right to examine the medical records of an impaired newborn infant (known only as Baby Jane Doe), whose parents had withheld consent to certain surgery and then refused to give HHS access to the infant's medical records. The District Court, on November 17, 1983, granted summary judgment against the government, holding that the hospital's failure to provide surgical treatment was the result of the parents' decision and not discrimination within the meaning of Section 504 and that, in any event, the par-

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[17] *See, e.g.*, J. Lyon, PLAYING GOD IN THE NURSERY 42-44 (1985); Affidavit of Richard L. Epstein ¶ 9 (J.A. 164-165); Affidavit of Peter A.M. Auld, M.D. ¶ 18 (J.A. 170-171); Affidavit of Rita G. Harper, M.D. ¶ 15 (J.A. 176). The AMA *et al.* submitted uncontested affidavits in support of their motion for summary judgment in this case. In her defense, the Secretary did not submit *any* testimonial evidence on medical issues. *See also* Affidavit of Paul M. Rosenberg (J.A. 178); Affidavit of Norman B. Urmy (J.A. 183) (harmful effects of inquiries in Rochester, N.Y. and Nashville, Tenn.).

[18] *See, e.g.*, Affidavit of Peter A.M. Auld, M.D. ¶¶ 12, 17 (J.A. 169-170); Affidavit of Rita G. Harper, M.D. ¶ 15 (J.A. 176). In addition, there is a significant risk that the arrival of federal Baby Doe squads will lead to painful and futile overtreatment which could injure not just the particular child being investigated but also other seriously ill children by depriving them of scarce places in hospital neonatal intensive care units. *See, e.g.*, Fost, *Baby Doe: Problems and Solutions*, 1984 ARIZ. ST. L.J. 637, 639; Affidavit of Peter A.M. Auld, M.D. ¶ 13 (J.A. 169).

ents' treatment decision had in all respects been reasonable. *United States* v. *University Hospital*, 575 F. Supp. 607 (E.D.N.Y. 1983). On February 23, 1984, the Court of Appeals affirmed on broader grounds, 729 F.2d 144 (Pet. App. 4a), holding that Section 504 does not "apply to treatment decisions involving defective newborn infants." (Pet. App. 40a). The Secretary declined to petition this Court for review of the Court of Appeals' decision in *University Hospital*.

b. *The Instant Case.* The Final Regulation was promulgated by the Secretary on January 12, 1984, while the *University Hospital* case was pending before the Court of Appeals. On March 12, 1984, the AMA *et al.* filed the instant action in the United States District Court for the Southern District of New York. (J.A. 129). On June 11, 1984, the District Court, under authority of *University Hospital*, issued a final judgment which (a) enjoined HHS from implementing the Final Regulation with respect to treatment decisions by parents and providers in individual cases involving impaired newborns and (b) enjoined HHS from otherwise investigating and regulating such decisions in the absence of a specific regulation on the subject, as HHS had done in its 49 investigations reported before publication of the Final Regulation. (Pet. App. 50a-52a). The Court of Appeals, also relying on the controlling effect of *University Hospital*, summarily affirmed the judgment in a two paragraph order. (Pet. App. 3a).[19]

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[19] Although she had lost in the District Court, the Secretary moved in the Court of Appeals for summary affirmance of the judgment striking down her regulatory regime, claiming that the earlier decision in *University Hospital* (which involved an HHS investigation of a single family) made plenary appellate review unnecessary. Although stating they were ultimately entitled to affirmance, the AMA *et al.* opposed summary disposition on the ground that, because HHS was clearly going to seek review in this Court, a fuller treatment of the issues relating to the Secretary's regulatory efforts would aid Supreme Court consideration. *See* J.A. 9 (docket entry). Accordingly, the AMA *et al.* will argue for affirmance on grounds similar to, but, in certain respects, distinct from, the reasoning of

SUMMARY OF ARGUMENT

Neither the express language of Section 504 nor its legislative history nor the general Section 504 regulation promulgated by HHS in 1977 mentions, let alone authorizes, direct federal involvement in the sensitive and complex issue of providing appropriate treatment in individual cases to severely impaired newborns. Nonetheless, since 1982, the Secretary has taken two types of actions asserting her authority to intrude directly in this most sensitive area of parent-child and physician-patient relations historically governed within a state law framework. She has issued notices and regulations, and she has investigated individual cases directly.

(A) Both HHS's regulatory pronouncements and its investigations have been aimed at instances where *parents do not consent to treatment* for their severely impaired infant. They have thus been aimed at a problem, not of discrimination between handicapped and non-handicapped, but at possible "medical neglect" in individual cases when parents do not authorize treatment for severely impaired newborns. The vexing question of when government should interfere with parents' choices for their infants in these complex, often tragic situations has historically been left to state authority under child abuse and neglect statutes. The related and equally vexing question of when physicians or hospitals should come between parents and their infant children and report parents for known or suspected neglect to state authorities has also been governed by these state statutes. In both its regulatory pronouncements and its actual investigations, HHS has unlawfully tried to turn these state law issues surrounding possible parental neglect into federal issues of discrimination against the handicapped in order to put direct federal pressure on parents through intrusive investigations. The judgment below declared this effort unlawful and

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the Court of Appeals in *University Hospital. See, e.g., Chevron U.S.A., Inc.* v. *NRDC*, 104 S. Ct. 2778, 2781 (1984); *Black* v. *Cutter Laboratories*, 351 U.S. 292, 297 (1956).

enjoined HHS from investigating and regulating individual treatment decisions by parents or providers either under the Final Regulation or under HHS's inherent Section 504 authority. In support of that judgment, respondents AMA *et al.* seek two related holdings barring HHS from intruding directly into state law issues of parental neglect.

First, the Secretary is not authorized by Section 504 to investigate and regulate parents' treatment decisions on behalf of their severely impaired newborns. The Secretary has changed her initial position and has now explicitly conceded that she has no authority under Section 504 to regulate parents directly. She has, thus, implicitly conceded that the judgment of the Court of Appeals in *University Hospital*, barring her from investigating parents who do not authorize treatment, was correct. Nonetheless, a holding of this Court is necessary, because *even after* stating in July 1983 that she had no authority to investigate non-treatment decisions of parents directly, the Secretary in November 1983 launched the oppressive pursuit of Baby Jane Doe's parents that resulted in the *University Hospital* decision. *See* Part I, *infra*.

Second, the Secretary has no authority under Section 504 to investigate and determine directly, before state executive and judicial officials have acted, whether health care providers have violated their state law duties to report known or suspected parental neglect to state authorities. The Secretary's theory here is so far beyond the scope of Section 504 that she barely attempts to defend it in her brief—and for good reason because it has not a shred of support in either the language or legislative history of Section 504. Moreover, this contorted interpretation violates basic rules of construction: it authorizes intrusive federal investigations which totally duplicate state responsibilities and thus constitute a forbidden "fundamental modification" of how health providers operate; it is not based on HHS's finding of a "particularly significant problem"; and it is not the product of the clear statement of congressional intent which

is necessary when the federal government attempts to regulate concurrently in an area historically left to the states. In sum, it simply cannot be that a health care provider could be held by HHS to have violated Section 504 for failing to discharge a *state law* reporting duty when there has been no final state determination by responsible state officials that state law has been violated. *See* Part II, *infra*.

(B) HHS's regulatory pronouncements and actual investigations have never been concerned with the wholly hypothetical case where *parents do consent to treatment* for their severely impaired infant but physicians refuse to provide it. In her brief to this Court, however, the Secretary has systematically distorted her regulatory statements, studiously ignored her actual investigations and misleadingly attempted to defend her actions on the basis of just such a hypothetical case—a case which bears no relationship to the regulatory regime invalidated below or to the world of medical practice. But HHS's attempt to retain intrusive investigative power in this area based on a hypothetical case is demonstrably unlawful.

Respondents AMA *et al.* thus also respectfully request this Court to hold that decisions by physicians in individual cases not to treat severely impaired infants are outside the scope of Section 504. There is no factual or rational basis under the Administrative Procedure Act for HHS regulation in this area. If parents consent to treatment for their impaired infants, physicians provide it. Despite HHS's development of a voluminous administrative record from 1982-1984, the Secretary has *never found or cited a single case* in which a physician has refused to provide treatment to a severely handicapped infant after the infant's parents have consented to such treatment. Moreover, neither the language nor legislative history of Section 504 evidences any Congressional intent to authorize direct HHS regulation of the "reasonableness" of physician decisions according to federal "504" standards of medical care established by the Secretary or to authorize an HHS investigation, before state

authorities have acted, of whether patient "abandonment," an area of medical practice traditionally regulated by the states, has occurred. *See* Part III, *infra.*

(C) By rendering these requested rulings and by thus invalidating HHS's actions against parents and health care providers in this most sensitive and complex area, this Court would not, of course, impair in any way Congress' authority in the future to amend Section 504 if it felt that the problem of appropriate treatment for severely impaired newborn infants warranted direct federal investigation and regulation of parental and provider decisions in individual cases. At issue is nothing more than the discretionary action of a single executive department, not a law of Congress. In this regard, it should be stressed that in the fall of 1984—the only time Congress addressed the question of what federal response to this complex issue is appropriate—Congress refused to authorize HHS's direct federal investigation and regulatory role in individual cases which had been invalidated earlier that year in this case. Instead, Congress used a state grant program and the existing state child protective service agencies to address the issue. In so doing, the sponsors of the law explicitly stated that HHS was prohibited under the Amendments from investigating treatment decisions in individual cases or from establishing federal treatment standards.[20] *See* pp. 47-48, *infra.*

ARGUMENT

The interests of severely impaired newborn infants are protected by their parents, by their physicians, by hospitals, by infant care review committees, by state child protective service agencies and by state courts. The question presented by this case is whether the Congress intended to authorize an additional level of federal involvement immediately after the birth of a severely impaired child and thus meant to empower the Secretary of HHS

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[20] *See* Child Abuse Amendments of 1984, Pub. L. No. 98-457, 98 Stat. 1749 (1984); 130 Cong. Rec. S12392 (daily ed. Sept. 28, 1984) (letter from Sen. Hatch to Sen. Weicker); HHS Br. 45 (no direct federal duties for providers created by 1984 Amendments).

to investigate and regulate directly the three decisions at issue in this case—decisions by parents not to consent to treatment, decisions by physicians when parents do not consent, and decisions by physicians when parents do consent. The answer mandated by the language of Section 504, its legislative history, sound principles of statutory construction and the Secretary's own concessions is clearly "no." [21]

I. THE SECRETARY HAS NO AUTHORITY TO INVESTIGATE AND REGULATE TREATMENT DECISIONS BY PARENTS ON BEHALF OF THEIR IMPAIRED NEWBORNS.

The historic right of parents in consultation with health care professionals to make treatment decisions for their minor children is bottomed on state common law and on the federal constitutional right of privacy.[22] As the Secretary recently stated:

> The decision to provide or withhold medically indicated treatment is, except in highly unusual circumstances, made by the parents or legal guardian. *Parents are the decision makers concerning treatment of their disabled infant, based on the advice and reasonable medical judgment of their physician.*

50 Fed. Reg. 14880 (1985) (emphasis supplied). Thus, absent a *state* court finding of medical neglect, final legal responsibility for making decisions about appropriate treatment of seriously ill newborns is vested exclusively in parents.[23]

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[21] The relationship between the three requested holdings and the judgment of the Court of Appeals is discussed at n.60, *infra*.

[22] State law has always recognized the parents' inherent right to make medical decisions on behalf of their children. *See, e.g., In re Hofbauer*, 65 App. Div. 2d 108, 411 N.Y.S.2d 416 (1978), *aff'd*, 47 N.Y.2d 648, 393 N.E.2d 1009 (1979); *In re Hudson*, 13 Wash. 2d 673, 126 P.2d 765 (1942). Parental autonomy to make decisions for their children is also protected under the Constitution. *See, e.g., Wisconsin* v. *Yoder*, 406 U.S. 205 (1972); *Pierce* v. *Society of Sisters*, 268 U.S. 510 (1925); *Meyer* v. *Nebraska*, 262 U.S. 390 (1923).

[23] *See* pp. 3-4, *supra*. A physician or hospital is guilty of battery if surgery is performed on an infant without parental consent. *See,*

A. HHS Concedes That Parents' Decisions Are Not Within The Scope Of Section 504.

In both the July 1983 proposed regulation and the January 1984 Final Regulation, the Secretary conceded that parental decisionmaking is outside the scope of Section 504. In the preamble to the Final Regulation, the Secretary stated: "Section 504 applies only to programs or activities receiving federal financial assistance; *it does not apply to decisions made by parents.*" 49 Fed. Reg. 1631 (1984) (J.A. 43) (emphasis supplied). Similarly, in the interpretative guidelines to the Final Regulation, the Secretary stated unequivocally: "Section 504 and the provisions of this part *are not applicable to parents (who are not recipients of Federal financial assistance).*" *Id.* at 1653 (J.A. 122) (emphasis supplied).[24] *See also* 48 Fed. Reg. 30848-30850 (1983); HHS Br. 5.

B. HHS's Efforts Have Nonetheless Been Aimed Almost Exclusively At Parents' Treatment Decisions.

Despite HHS's concession in July 1983 and January 1984, its regulatory regime has unmistakably been aimed at parents' decisions involving treatment for their severely impaired newborns. Indeed, the "Baby Doe of Indiana" case, which gave rise to the 1982 Notice and all subsequent regulations in this area, involved a decision by parents not to authorize treatment for their child, as the Secretary now explicitly acknowledges for the first time. HHS Br. 2.[25] The 1982 Notice, the 1983 Interim Rule,

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e.g., W. Prosser & W. Keeton, HANDBOOK OF THE LAW OF TORTS § 18, at 116 (5th ed. 1984).

[24] In light of HHS's concessions, the argument by analogy in the *University Hospital* dissent—that "denial of medical treatment to an infant because the infant is black is not legitimated by parental consent"—is clearly in error. (Pet. App. 44a). Regardless of the race, color, creed or impairment of an infant, health care providers have no authority to operate on a child without parental consent or without a court order removing the parent as decisionmaker for the child. Neither Title VI of the Civil Rights Act of 1964, 42 U.S.C. §§ 2000d *et seq.*, nor Section 504 alters this fundamental rule.

[25] *See* note 10, *supra*. In each of her regulatory pronouncements in this area, as well as in her petition (Pet. 2-3, 17, 20, 22), the

the 1983 proposed rule and the 1984 Final Regulation have all in significant respects been aimed directly at parents' decisions. *See American Academy of Pediatrics, supra*, 561 F. Supp. at 400 ("primary purpose" of interim rule "to prevent parents" from making decisions), 401 (same). Most importantly, virtually all of the 49 investigations reported by HHS in the preamble to the Final Regulation have been aimed directly at parental decisions. *See* pp. 11-13, *supra*.

In fact, the oppressive actions of the Secretary in *University Hospital*—which have been conspicuously absent from her description of that case in this Court (Pet. 8-9; HHS Br. 9-11)—conclusively demonstrate that the purpose of the Secretary's regulatory approach is to interfere with parental decisions not to authorize treatment. After Baby Jane Doe was born with multiple birth defects on October 11, 1983, her parents decided not to consent to certain surgery following consultation with "several physicians, nurses, religious advisors, a social worker, and members of their family." (Pet. App. 6a). The state courts of New York rejected the claim of a third party, unrelated to Baby Jane Doe, seeking appointment of a guardian *ad litem* and an order directing that surgery be performed.[26]

While the state court proceedings were still in progress, HHS, which had received a Section 504 complaint from an unidentified person, referred the matter to the New York state child protective service agency. (Pet. App. 8a).

Secretary has relied on the "Baby Doe of Indiana" case as justification for her regulatory approach, although it involved a decision by parents not to authorize treatment, which the Secretary now concedes is outside the scope of Section 504. *See* 47 Fed. Reg. 26027 (1982) (J.A. 127); 48 Fed. Reg. 9631 (1983); 48 Fed. Reg. 30847 (1983); 49 Fed. Reg. 1623 (1984) (J.A. 14). *See also* 49 Fed. Reg. 1646 (1984) (J.A. 96) (summarizing HHS's formal investigation of case).

[26] The trial court granted this request, but was immediately overruled by the Appellate Division, which determined that the parents' decision was in the best interests of the child. (Pet. App. 7a). The New York Court of Appeals affirmed on October 28, 1983. (Pet. App. 7a-8a).

Without waiting for the state agency to make its determination, HHS in late October began its own direct Section 504 investigation, repeatedly requesting the patient's records. (Pet. App. 8a). University Hospital declined to give Baby Jane Doe's medical records to HHS, based in part on the parents' refusal to release them. On November 2, 1983, *before* the state child protective service agency had reached a decision, HHS and the Department of Justice brought a federal court action under Section 504 seeking access to the records to determine if the parents were making a reasonable medical decision. The government then persisted in its suit even after the state courts had refused to override the parents' choice and after the state agency concluded on November 7, 1983 that no state intervention was warranted under New York's child neglect statute. (Pet. App. 8a-11a).

To protect their interests, Baby Jane Doe's parents were forced to intervene in the federal suit, after defending a state court action and answering a state child protective service agency inquiry. This harassing federal lawsuit, which ignored state administrative and judicial decisions, exposed the parents to continued, unwanted publicity and imposed on them over $75,000 in additional legal fees. *See* 130 Cong. Rec. S8017 (daily ed. June 21, 1984). Given her explicit concession that she has no authority under Section 504 to investigate parents, the Secretary has implicitly conceded that the result in *University Hospital*—barring her investigation of Baby Jane Doe's parents—was correct and her harassing lawsuit was completely unjustified.[27]

C. An Affirmance On This Issue Is Necessary.

Notwithstanding HHS's concession of July 1983 and January 1984 that it is forbidden, under Section 504,

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[27] HHS can hardly argue with any credibility that it was seeking to investigate whether physicians or hospitals were discharging their duties under state law to report parental neglect since the suit was brought while the state agency was considering the issue of parental neglect and continued after the agency determined there was no such neglect.

to investigate or regulate individual treatment decisions of parents, a holding of this Court on this issue is necessary for two related reasons. First, such a holding is required to ensure that the Secretary does not unlawfully continue to investigate parents and thereby to ensure that *University Hospital* will never be repeated. Despite the July 1983 concession in the proposed regulation, 48 Fed. Reg. 30848 (1983), the Secretary nonetheless commenced, in October and November of 1983, the Baby Jane Doe investigation and lawsuit that led to the decision in *University Hospital.* Indeed, following her concession in July 1983, the Secretary launched at least 12 investigations which appear to have been directed solely at parents' decisions not to authorize treatment and which were stopped only when the injunction was entered in this case. (J.A. 103-105; cases No. 38-No. 49).

Second, three of the four mandatory provisions of the Final Regulation are aimed directly at parental decision-making. The notice which hospitals must post under the Final Regulation is unquestionably aimed at parents because it recites that any withholding of medically beneficial care from an impaired newborn violates Section 504, with no suggestion, much less clarification, that Section 504 is wholly inapplicable if such decisions are made, as they must be, by parents. 45 C.F.R. § 84.55(b) (J.A. 112-114).[28] Similarly, the mandatory provisions authorizing expedited HHS access to infant medical records and expedited compliance actions do not clearly exclude treatment decisions by parents from HHS's reach; they broadly establish HHS's authority both to investigate the parents' decisions concerning the course of treatment for their impaired infant child and to institute a federal court action to override the parents' decision, as HHS's own investigations demonstrate. 45 C.F.R. § 84.55(d),

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[28] *See* 49 Fed. Reg. 1625-1626 (1984) (J.A. 23-27) (refusal of HHS to make non-applicability to parents clear in notice, despite concession that Section 504 does not apply to parental decisions).

§ 84.55(e) (J.A. 115-116).[29] Thus, a holding by this Court that Section 504 does not apply to parents' treatment decisions is also necessary to invalidate three of the four mandatory provisions of the Final Resolution.[30]

II. THE SECRETARY HAS NO AUTHORITY TO INVESTIGATE AND DETERMINE, BEFORE STATE OFFICIALS HAVE ACTED, WHETHER PHYSICIANS ARE DISCHARGING THEIR STATE LAW DUTIES TO REPORT MEDICAL NEGLECT BY PARENTS.

Having been forced to admit that she cannot investigate and regulate parents' decisions not to consent to treatment for their infant, the Secretary in the Final Regulation impermissibly asserts her authority to do indirectly what she concedes she cannot do directly—to pressure parents by investigating and determining, before state authorities have acted, whether health care providers are discharging their duties under state law to report parental "medical neglect" to state authorities. This contorted view of Section 504 violates the statute because HHS is investigating neglect of a single child, not discrimination between the handicapped and non-handicapped —an investigation which will necessarily and impermissibly require HHS to determine, before state authorities have acted, whether the level of care requested by parents is adequate under varying state standards of medical care in these complex cases. This application of Section 504 is, to use Justice Powell's phrase, not only an illegal but also an "unedifying example of over-zealousness on the part of the Federal government." *Grove City College* v. *Bell*, 104 S. Ct. 1211, 1223 (1984).

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[29] The expedited access to medical records is designed to enable HHS investigators to review and monitor the treatment of infants, which is the prerogative of parents.

[30] The other mandatory provision of the Final Regulation, 45 C.F.R. § 84.55(c) (J.A. 114-115), relates solely, for purposes of this case, to HHS's authority directly to investigate and regulate health care providers, not parents. *See* pp. 25-27.

A. HHS Has Arrogated To Itself State Law Functions.

As noted, under the statutes of all 50 states, health care providers have a duty to report to state authorities known or suspected instances of medical neglect by parents. Similarly, allegations that health care providers themselves have not discharged their statutory reporting duty are investigated by the state's child protective service agencies or prosecutors. Thus, any health care provider's failure to discharge the state law duty to report known or suspected instances of medical neglect must be adjudicated ultimately in state court—and a violation of that duty can lead to a criminal prosecution and criminal sanctions.[31]

With respect to cases where parents do not consent to treatment, the Secretary in the Final Regulation shifted position and claimed that she may investigate directly and immediately after the birth of a severely impaired child the issue of whether health care providers are discharging their *state law duties* to report parental medical neglect. Section 84.55(c) of the Final Regulation (J.A. 114; emphasis supplied) requires, under "authority pursuant to State law" that "health care providers report on a timely basis *to the state agency* circumstances which they determine to constitute *known or suspected instances of unlawful medical neglect* [by parents] of handicapped

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[31] The child abuse and neglect statutes in all 50 states impose upon physicians, and other health care professionals, a mandatory reporting duty which arises whenever the provider either knows of or suspects, or has reasonable cause to know of or suspect, the occurrence of child abuse and/or neglect. Each statute designates a state welfare and/or law enforcement agency as having responsibility for receiving reports, conducting investigations and initiating appropriate judicial proceedings. The failure of a physician or other health care official to report a suspected instance of abuse or neglect to the requisite agency is punishable in every state by criminal or civil penalties or both. *See* R. Horowitz & H. David., LEGAL RIGHTS OF CHILDREN § 7.12 (1984). *See also e.g.*, CAL. PENAL CODE § 11172(d) (West Supp. 1985); ILL. REV. STAT. ch. 111, § 4433 (Smith-Hurd Supp. 1984-1985); MASS. ANN. LAWS ch. 119, § 51A (Michie/Law. Co-op. Supp. 1985); N.Y. SOC. SERV. LAW § 420 (McKinney 1983).

infants." Similarly, the interpretative guidelines to the Final Regulation state (J.A. 122; emphasis supplied):

> Section 504 . . . [is] not applicable to parents. However, each recipient health care provider must in *all aspects* of its health care programs receiving Federal financial assistance provide health care and related services in a manner consistent with the requirements of Section 504 . . . . *Such aspects includes* [*sic*] *decisions on whether to report, as required by State law . . . , to the appropriate child protective services agency a suspected instance of medical neglect of a child* [by its parents]. . . .

As the preamble states (49 Fed. Reg. 1631; J.A. 44; emphasis supplied):

> [T]he proper analysis of the applicability of section 504 in cases where the failure to provide medically indicated treatment is due to a lack of parental consent is that a recipient hospital *is not required to seek to unilaterally overrule the parents*, but it must adhere to the standard practice, *as required by state law*, to make a report to the state agency . . . .[32]

Although the Secretary uses violations of state reporting duties as the predicate for a finding of discrimination, she does not leave the determination of whether physicians have discharged their reporting duties under state law to the duly constituted state executive and judicial authorities. Rather, the Secretary asserts her authority, under Section 504, to make an independent investigation and determination even before state authorities have acted.[33] Implicit in this determination is the issue of whether the child is receiving medicaliy indi-

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[32] The proposition that the physicians' reporting duty is based on state law is repeated throughout the preamble to the Final Regulation. 49 Fed. Reg. 1624, 1627, 1631, 1644 (J.A. 19, 27-28, 44, 90). *See also* 48 Fed. Reg. 30848-30849 (1983); Pet. 6; HHS Br. 7, 27.

[33] 49 Fed. Reg. 1632 (1984) (J.A. 47-48). Section 84.55(d), as noted, provides for "expedited access" to records, including access at any hour of the day or night. (J.A. 115). Section 84.55(e) provides for "expedited action to effect compliance," and HHS claims authority to do this without providing notice to the hospital or physician. (J.A. 115-116).

cated treatment under state law standards. Only if a child's parents do not appear to be authorizing adequate care is there a basis for a physician to report the parents to state authorities for possible neglect. Incredibly, the Secretary thus claims the power in a federal administrative proceeding to make a determination of the adequacy of treatment under state law standards of medical care in these complex cases (standards which may vary from state to state) in order to see if physicians' reporting duties have been violated. Thus, the Secretary claims that HHS, a federal agency with no power to enforce any state's law, can *immediately* determine when there has been a "failure [by a provider] to comply" with varying *state law reporting requirements* in each of the 50 states and can seek a temporary restraining order to stop such *state* law violations. 49 Fed. Reg. 1628 (1984) (J.A. 33).

B. HHS's Arrogation Of State Law Functions To Itself Does Violence To The Language Of Section 504.

The Secretary's claimed ability to substitute her "Baby Doe squads" for state child protective agencies, state prosecutors and even state courts in determining whether health care providers have violated state law reporting duties is demonstrably not authorized by the language of Section 504. The Secretary's brief makes virtually no attempt to show that her claimed authority is supported by the words of the statute—and no such showing is possible. HHS Br. 27.

1. *"Otherwise Qualified" And "Subjected To Discrimination."* In *Alexander* v. *Choate*, 105 S. Ct. 712, 720 n.19 (1985), this Court stated that the "question of who is 'otherwise qualified' and what actions constitute 'discrimination' under" Section 504 "would seem to be two sides of a single coin." When parents of a severely impaired child do not consent to medical treatment in a federally funded health program, the child is not "otherwise qualified" for such treatment within the terms of Section 504. In such circumstances, recipients of federal health care funds do not fail to provide treatment in a federally funded health program solely on the basis of the child's

handicap, but rather solely on the basis of the child's infancy.[34] The Secretary does not—and cannot—dispute this unassailable conclusion which removes federally funded hospitals from the reach of Section 504 when parents do not consent to treatment on behalf of their child. HHS Br. 21-26.

Instead, in an improper attempt to bring federally funded hospitals within the reach of Section 504 in a situation involving potential parental *neglect* of a single child—not *discrimination* between an impaired child and a non-impaired child regarding access to a federally funded health program—the Secretary simply asserts without citation that, under the "subjected to discrimination" language of Section 504, health care providers may not fail to discharge their state law duties to report the parents of severely impaired children to state law authorities. HHS Br. 27. But only when there has been such a final state law determination of a physician's reporting violation, which would involve complex medical and legal considerations in individual cases under the varying laws of each state, could HHS even conceivably begin to determine whether the violation constituted "discrimination" against the severely impaired child within the meaning of Section 504.

It must be emphasized that, in making such a determination, HHS would necessarily and impermissibly have

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[34] In *Southeastern Community College* v. *Davis*, 442 U.S. 397, 406 (1979), this Court stated that the plain meaning of "otherwise qualified handicapped individual" is "one who is able to meet all of a program's requirements in spite of his handicap." When parents do not provide consent to treatment for a severely impaired child, one of the requirements of a health care program—consent to treatment—is not present and thus the severely impaired child is not "otherwise qualified" for treatment in that program.

Nor does HHS even attempt to show that an impaired newborn is "otherwise qualified" to have a recipient of federal funds in a *health care program* provide access, not to that federally funded health care program, but instead to state administrative and judicial processes for determination under state law standards of the parents' fitness to make medical decisions on the infants' behalf when its parents have not consented to treatment.

to determine the adequacy of the care a child was receiving under the varying standards of medical care in the 50 states because only if the care requested by parents is, or appears to be, inadequate are physicians required under state law to report parents for possible neglect. *See* note 31, *supra*. In its brief, HHS never addresses this obvious and fatal implication of its regulatory approach—which is built on the distinction between *bona fide* and discriminatory care in individual cases (HHS Br. 16)—and thus never attempts to respond to the basic holding of the Court of Appeals in *University Hospital* that determinations by HHS of the standard of medical care in individual cases is simply not authorized by Section 504. HHS Br. 26-38.[35] Thus, the express language of Section 504 demonstrably does not authorize the Secretary to make an independent federal investigation and determination of whether recipients of federal health care funds have violated state child abuse and neglect laws—including the necessary determination of whether a child has received appropriate medical care under state law standards—*before* a final state court judgment to that effect.[36] *See* pp. 25-27, *supra*.[37]

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[35] Neither the language, nor the legislative history, *see* pp. 42-45, *infra*, of Section 504 authorizes such an unprecedented expansion of federal power, as the Court of Appeals correctly held. *See* Pet. App. 30a-31a ("subjected to discrimination" language of Section 504 does not authorize HHS to establish standard of medical care for distinguishing *bona fide* medical judgments from discriminatory ones).

Respondents AMA *et al.* do not maintain, by this discussion, that a violation of a state reporting duty, as determined by a final state court judgment, would give rise to a Section 504 violation. That issue is not before this Court. Our position is only that no Section 504 action is even conceivable without such a final judgment.

[36] The issue of whether, and to what extent, the Secretary can investigate and regulate the enforcement practices of state child protective service agencies which receive federal child abuse funds—as opposed to the state law reporting duties of health care providers who receive federal health care funds—is not presented in this case.

[37] There are occasional HHS statements that "discriminatory" applications of hospitals' "policies" and "practices" of either report-

2. *"Program Or Activity Receiving Federal Financial Assistance"*. This Court has made clear that simply because an entity, including a hospital, receives federal money does not mean that every action taken by that entity is subject to the federal antidiscrimination ban under Title VI, Title IX or Section 504. Instead, the phrase "program or activity" is a limiting concept and the duties created by those statutes are program-specific in their reach. *Consolidated Rail Corp.* v. *Darrone*, 104 S. Ct. 1248, 1255-1256 (1984); *Grove City College* v. *Bell*, 104 S. Ct. 1211, 1220-1222 (1984); *North Haven Board of Education* v. *Bell*, 456 U.S. 512, 538 (1982).

In support of her claimed authority to regulate physicians' state law reporting duties, the Secretary simply asserts in a single sentence, without citation, that the physicians' duty, established under state statute, to report parental medical neglect to state authorities is part of a federally funded "program or activity." HHS Br. 27. But this assertion is certainly not supported by the plain meaning of Section 504. It is, to the contrary, a very contorted use of the term "program," in the context of the provision of health care, to apply it to a physician's decision required solely by state law to report parents of infant children to state authorities for enforcement of the state's neglect statute. Indeed, in its brief, HHS concedes that the Final Regulation has made no showing that these state law reporting duties are part of a federally funded program or activity. HHS Br. 21 n.9. As a matter of

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ing parental neglect or seeking court orders displacing parents as decisionmakers may violate Section 504. 49 Fed. Reg. 1631 (J.A. 43); HHS Br. 27. The short answer to that erroneous contention is that the Final Regulation itself is clearly restricted to enforcing the *state law* duties of hospitals and physicians. *See* 45 C.F.R. § 84.55(c) (J.A. 114-115) and pp. 25-27, *supra*. Moreover, since such "practices" in fact involve nothing more than the hospital's efforts to comply with state law (in the case of reporting "neglect") or to make state law judgments (in the case of taking "neglectful" parents to court), HHS's investigations of such "practices" would necessarily, and improperly, require HHS to make state law judgments *based in part on its own view of state standards of medical care in individual cases.*

law, at least a *minimal* showing by HHS that the activity being regulated is part of a federally funded "program or activity" should be required before such intrusive regulations are allowed.[38]

C. HHS's Arrogation Of State Law Functions To Itself Is Not Authorized By The Legislative History Of Section 504.

The legislative history of Section 504 also does not authorize the Secretary to make an independent investigation and determination whether a health care provider who is the recipient of federal health care funds is violating reporting duties established by state child neglect statutes before state executive and judicial officials have acted. HHS's 15-page discussion in its brief (pp. 29-44) of the legislative history of Section 504 adduces *no* authority from the congressional deliberations to support its contorted position that it has authority to make state law judgments before state authorities do.[39]

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[38] The legal requirement that a regulation must have a factual basis to justify the burdens it imposes is derived from both the Administrative Procedure Act, 5 U.S.C. §§ 551 *et seq.*, and Section 504. The APA requires every agency rule to be supported, at a minimum, by a reasonable basis in fact. *See* page 40, *infra*. In addition, it would be fundamentally inconsistent with the limitations in the scope of Section 504, recognized by this Court in *Alexander* v. *Choate*, 105 S. Ct. 712 (1985) (page 32, *infra*), to allow an agency to delve into a new area of enforcement, never contemplated by Congress, without making at least a minimal showing that the decisions being regulated are related to some federally funded activity. But as noted above, the Secretary has conceded that she has made no such showing with respect to physicians' state reporting duties. HHS Br. 21 n.9.

[39] During the course of its discussion of the legislative history, HHS also discusses the general Section 504 regulation which was promulgated in 1977 to implement the legislation and which was subsequently cited in the 1978 amendments to Section 504. HHS Br. 39-44. Again, HHS cites *nothing* in that general regulation which authorizes HHS to investigate and determine violations of state law reporting duties before state officials have acted. *See also* pp. 42-45, *infra* (legislative history of Section 504 provides no authority for HHS to apply *state* standards of adequate medical care to individual cases or to establish *federal* standards of medical care for evaluating such cases).

D. HHS's Arrogation Of State Law Functions To Itself Violates Basic Canons Of Section 504 Construction.

Although the Secretary's attempt to make state law judgments before state officials have acted is clearly not authorized by the language and legislative history of Section 504, any ambiguity on the reach of the statutory language clearly must be resolved against the Secretary. This Court has held that the determination of the scope of Section 504 must be responsive to two powerful but countervailing considerations—the need to give effect to the statutory objectives of protecting the beneficiaries of the Act and the desire to keep Section 504 within manageable bounds. *Alexander, supra*, 105 S. Ct. at 720. This Court in *Alexander* thus restated the fundamental rule of Section 504 construction set forth in *Southeastern Community College* v. *Davis, supra* (105 S. Ct. at 720; emphasis supplied):

> *Davis* thus struck a *balance* between the statutory rights of the handicapped to be integrated into society and the legitimate interests of federal grantees in preserving the integrity of their programs: *while a grantee need not be required to make "fundamental" or "substantial" modifications to accommodate the handicapped, it may be required to make "reasonable" ones.*

Thus, in contrast to other civil rights statutes, such as Title VI, Section 504 requires the judiciary to make an independent inquiry into the reasonableness of HHS action when it is not clearly authorized by the Congress.[40]

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[40] Unlike race, which never is a *bona fide* consideration underlying any particular decision unless used to remedy the effects of past discrimination, handicap may be a relevant factor in deciding whether someone is qualified for access to federally funded programs. For this reason Section 504 cannot be and has not been interpreted by this Court in the same way as a statute such as Title VI, even though Section 504 was in broad outline patterned after Title VI. *See Alexander* v. *Choate*; Note, *Employment Discrimination Against The Handicapped and Section 504 of the Rehabilitation Act: An Essay On Legal Evasiveness*, 97 HARV. L. REV. 997, 1006-1007 (1984). Instead, in a case such as this, the Court must decide whether the accommodation HHS has required health care providers

1. But HHS cannot satisfy the basic rule of construction established in *Alexander*. Its efforts to investigate and regulate directly physicians' state law reporting duties constitute a forbidden "substantial modification" of the providers' health program (even assuming, as we do not, that a federally funded hospital's state law reporting duties are part of any federally funded "program or activity," *see* pp. 30-31, *supra*). Before HHS's regulatory efforts in this area, hospitals and physicians had to respond to investigations by state agents of state law reporting duties and defend court actions brought for failure to discharge such duties. Now, however, the Secretary claims that health care providers also must submit to independent, duplicative and wholly improper state-law-based investigations by HHS in the hours and days after the birth of a severely impaired newborn. Before state authorities have acted, physicians must also defend themselves in an HHS fund withdrawal proceeding which must be bottomed, implausibly, on HHS's determination of whether state law reporting duties have been violated—a determination which necessarily requires HHS in a *federal* forum to show that state standards of reasonable medical care have not been followed and which would necessarily force hospitals and physicians to rebut that showing in these unprecedented "504 malpractice" cases. This is demonstrably a "substantial" modification in the practices of hospitals and physicians because it involves the imposition of a "wholly unwieldy administrative and adjudicative burden" forbidden by *Alexander*. 105 S. Ct. at 719.

Moreover, HHS requires interviews by federal "Baby Doe" squads with physicians, nurses and other professionals; it requires making records available to federal investigators. It thereby has the potential for duplicating any investigation by the state authorities who are duly constituted under state statute to determine whether state reporting laws are being followed. It is hard to imagine

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to make to protect handicapped infants is a reasonable one. *Alexander, supra*, 105 S. Ct. at 720.

a more "substantial" or "fundamental" modification in a program of health care for newborns—a modification which is *not* necessary because HHS simply cannot make state law judgments before state authorities do. Moreover, not only is this a substantial modification, but it is also one which actually causes harm as the uncontradicted record below demonstrates. *American Academy of Pediatrics, supra*, 561 F. Supp. at 396, 399-400 (HHS approach causes "profound change" in way care provided).[41]

2. In *Alexander* v. *Choate*, this Court also stated that the Secretary will have "substantial leeway to explore areas in which discrimination against the handicapped posed *particularly significant problems* and to devise regulations to prohibit such discrimination." 105 S. Ct. at 722 n.24 (emphasis supplied). But despite her attempt to find in that sentence a roving commission to take any action she deems appropriate, HHS Br. 29, 36, it, in fact, offers another reason, if one is needed, to strike down the Secretary's efforts in this area. In *Alexander*, the Court was referring to "particularly significant problems" which had been identified in the general Section 504 regulation promulgated in 1977 by HEW (the predecessor department for these purposes to HHS) and recognized by the Congress in 1978 amendments to Section 504. 105 S. Ct. at 724 n.27. But, there was simply no discussion in those regulations of what HHS itself has conceded are the unique and complex issues surrounding treatment for severely impaired newborns,[42] let alone any mention of the

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[41] *See* p. 12, *supra*. Indeed, even HHS's cursory description of its own reported investigations makes clear that they have resulted in invasions of family privacy, medical records and confidential medical decisionmaking, and have disrupted hospital operations and delayed ongoing treatment for impaired newborns and other patients. (J.A. 95-106). *See also* Shapiro & Rosenberg, *The Effects of Federal Regulations Regarding Handicapped Newborns: A Case Report*, 252 J.A.M.A. 2031 (1984); Strain, *The American Academy of Pediatrics Comments on the "Baby Doe II" Regulations*, 309 NEW ENG. J. MED. 443 (1983); J.A. 162-186 (unrebutted affidavits submitted in this case).

[42] *See* 49 Fed. Reg. 1636 (1984) (J.A. 61) (noting that application of Section 504 in this area is "much more subtle and difficult" than

need for HHS independently to make state law judgments regarding reporting duties of providers under state child abuse and neglect laws before state officials have acted.

Moreover, the Department has itself failed in the administrative record to demonstrate that there is any problem—let alone a particularly significant one—with providers' failure to discharge such reporting duties *and* with state agencies' failure to enforce those duties. In the 1984 Child Abuse Amendments—the only instance in which the Congress has addressed the question of appropriate care for impaired infants—the Congress sought to strengthen the authority of state agencies, not supplement or supplant it with a duplicative federal role as proposed by the Secretary. *See* pp. 47-48, *infra*; HHS Br. 28, 45. Moreover, in the regulations implementing the 1984 Child Abuse Amendments, the Secretary noted that "only a very small fraction of births involve any serious question of survival" and only "a fraction" of this tiny fraction would "involve even a potential allegation of [parental] medical neglect" under state law. 50 Fed. Reg. 14886-14887 (1985). In fact, the Secretary further conceded in the 1984 Child Abuse Regulation that use of infant care review committees should reduce the already minuscule need for formal *state* legal proceedings against parents involving impaired newborns to a "[v]ery few cases." *Id.* It follows, *a fortiori*, that the problem of health care providers failing to *report* parental neglect is even smaller, and the problem of state agencies failing to deal with such cases is virtually non-existent. *See also* HHS Br. 2-11, 28 (*no* mention of any problem).[43] Accordingly, no

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other areas); *id.* 1632 (J.A. 45-46) (few "definitive statements" on application of Section 504 in this area possible); *id.* 1654 (J.A. 123) ("special circumstances" of each case).

[43] HHS Br. 6 (federal "enforcement" is "unnecessary" given infant care review committees). Nothing in the Final Regulation demonstrates any reporting problem of federal dimensions. The single case noted by HHS did not, by HHS's own account, involve determination of a state law or Section 504 violation, but only the voluntary resolution of a complaint when a hospital stated it would do what it was obligated to do anyway: follow state law. HHS Br. 44; 48 Fed.

deference is due to the Secretary's attempt to regulate a non-existent problem and, therefore, her construction of Section 504 in this regard should be rejected. *See also Skidmore* v. *Swift & Co.*, 323 U.S. 134, 140 (1944); *General Electric Co.* v. *Gilbert*, 429 U.S. 125, 143 (1976) (inconsistent agency interpretation owed no deference).[44]

E. HHS's Arrogation Of State Law Functions To Itself Violates Sound Principles Of Federalism.

The Secretary's assertion of authority to disregard traditional state processes for responding to suspected medical neglect and to investigate and regulate directly health care providers' conduct before the state acts evidences a striking lack of respect for the states and violates another fundamental rule of construction which requires a clear statement of congressional intent. The Secretary makes no effort in either the administrative record or her brief to explain why, given her reliance on state law as the basis for judging physicians' conduct, she is completely unwilling to defer to the states to make state law judgments. This disrespect for the states stands in stark contrast to how the Congress itself ordinarily treats concurrent federal and state enforcement efforts. For instance, in both

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Reg. 30847 (1983). The other cases and studies cited in the Final Regulation do not even address the only relevant question of whether there is some problem with the state child protective service agencies which justifies HHS investigations, not of those agencies themselves, but of the health care professionals regulated by those agencies before those agencies have acted. *See* 49 Fed. Reg. 1645 (1984) (J.A. 90-93).

[44] With respect to situations where parents refuse to consent to treatment, HHS has shifted position dramatically in a short period of time. First, it said physicians should discharge patients from hospitals; then it indicated in its Interim Rule and argued to Judge Gesell that physicians should simply provide treatment against the parents' wishes; and, only when it finally realized that parents have ultimate legal responsibility for their children absent a neglect finding, did it focus on physicians' state law reporting duties. *See* pp. 7-11, *supra*; 49 Fed. Reg. 1631 (1984) (J.A. 43-44). *See also American Academy of Pediatrics, supra*, 561 F. Supp. at 400 (Interim Rule product of "haste and inexperience").

Title VII, 42 U.S.C. § 2000e-5(d), and the Age Discrimination in Employment Act, 29 U.S.C. § 633(b), Congress expressly required federal agencies to refer all discrimination claims in the first instance to a state agency if the state has a parallel anti-discrimination statute. *See Oscar Mayer & Co.* v. *Evans*, 441 U.S. 750, 756 (1979). It is completely incongruous to think that the same Congress intended to authorize HHS in the guise of a federal civil rights statute for the handicapped to enforce physicians' state law reporting duties within hours and days after birth without any deference to the investigations and determinations of state agencies and courts.

Indeed, the Secretary's proposed effort to modify the "federal-state balance" by intruding into the states' traditional regulation of medical neglect cases could only be justified by a clear statement of congressional intent to permit this regulation. *See FTC* v. *Bunte Brothers, Inc.*, 312 U.S. 349, 354-355 (1941); *Apex Hosiery Co.* v. *Leader*, 310 U.S. 469, 513 (1940); *United States* v. *Bass*, 404 U.S. 336 (1971). *Cf., Pennhurst State School & Hospital* v. *Halderman*, 451 U.S. 1, 17 (1981).[45] This Court, in reviewing federal attempts to regulate behavior *concurrently* with the states, has held that, absent a "clear statement" of congressional intent, the federal action was prohibited. That rule applies with special force in this case. Here the Secretary is acting in an area historically ceded to the states: the regulation of sensitive parent-child and physician-patient relationships, under the states' *parens patriae* and police powers. *See* pp. 3-4, *supra*. Thus, this case is even more extreme than other "concurrent regulation" cases requiring a clear statement of Congressional intent because the duties of the health care providers to report parental neglect which the Secretary seeks to regulate arise *solely* under state law. Absent a clear statement from the Congress, the Secretary simply may not precede, duplicate and/or supplant state execu-

[45] *See, e.g., Williams* v. *United States*, 458 U.S. 279, 290 (1982); *United States* v. *Enmons*, 410 U.S. 396, 411 (1973); *Palmer* v. *Massachusetts*, 308 U.S. 79, 83-85 (1939).

tive and judicial authorities who investigate and determine whether state law reporting duties have been violated by health care professionals.[46]

III. THE SECRETARY HAS NO AUTHORITY TO INVESTIGATE AND REGULATE PHYSICIANS' TREATMENT DECISIONS IN INDIVIDUAL CASES.

In addition to her unlawful application of Section 504 to providers' duties under state law to report for neglect parents who do not authorize treatment, the Secretary has also claimed authority to apply the statute to decisions by providers not to treat impaired newborns. HHS Br. 13. Such provider decisions not to treat can arise in only two circumstances: when parents have not consented to treatment for their child and when they have. In neither circumstance is action by the Secretary lawful.

A. Providers' Decisions Not To Treat In Cases Where Parents Have Withheld Consent To Treatment.

In the preamble to the Final Regulation, HHS finally conceded that health care providers have no authority to treat an infant over parents' objections and that, as a result, providers' treatment decisions in these circumstances are wholly beyond the purview of Section 504. *See, e.g.*, J.A. 43-44; HHS Br. 27-28. Nevertheless, because HHS has in previous statements—most notably in the Interim Rule, 48 Fed. Reg. 9630 (1983)—asserted authority under Section 504 to require providers to treat infants over their parents' objections, and has ignored other concessions in prosecuting *University Hospital*, it is appropriate that this Court formally hold that Section 504 does not apply to providers' treatment decisions when the parents have withheld consent to treatment.

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[46] HHS's efforts to enforce parental neglect reporting duties are also invalid under the fundamental rule of construction that a government agency or department cannot do indirectly what it is prohibited from doing directly (*i.e.*, regulate parents' decisions). *See T.I.M.E., Inc.* v. *United States*, 359 U.S. 464 (1959). *See also Montana-Dakota Utilities Co.* v. *Northwestern Public Service Co.*, 341 U.S. 246 (1951); *Sunray Mid-Continent Oil Co.* v. *FPC*, 364 U.S. 137, 152 (1960).

B. Providers' Decisions Not To Treat In Cases Where Parents Have Authorized Treatment.

In this Court, HHS devotes virtually all of its brief to the argument that it is authorized under Section 504 to investigate and regulate directly providers' decisions not to provide treatment when parents have given their consent. But this Court need not even reach this issue of construction because the application of Section 504 to such decisions is clearly unlawful under the Administrative Procedure Act ("APA"). 5 U.S.C. § 551 *et seq.*[47] In any event, this application of the Regulation is also not authorized by Section 504.

1. *The Application Of The Final Regulation To Such Decisions Is Arbitrary And Capricious.*

Because the application of Section 504 to provider decisions not to treat in individual cases invades an area traditionally governed by state law processes, the Secretary may regulate them, if at all, only on the basis of a valid, *specific* regulation. Under *Alexander* v. *Choate*, she cannot rely solely on any inherent Section 504 authority under the statute or the general implementing regulations.[48] But, the Final Regulation cannot provide her such specific authority because application of that regu-

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[47] *See* J.A. 146-147 (respondents AMA *et al.* alleged APA count in their complaint) and note 19, *supra* (this Court may affirm judgment on alternate ground).

[48] In *Alexander*, this Court held that the Secretary could not, simply on the authority of the "generally-worded" Section 504 regulations promulgated in 1977, intrude on the states' traditional discretion in administering Medicaid, a federal/state program, if such action was not explicitly authorized by the statute, its legislative history or the general regulation. 105 S. Ct. at 724 & n.32. The need for a specific implementing regulation before the Secretary may act is even stronger with respect to physicians' treatment decisions where the application of Section 504 is wholly unprecedented, intrudes on existing state law standards governing the reasonableness of medical practice in individual cases, and is not explicitly authorized. *Cf.*, 42 U.S.C. § 1395 (disavowing federal supervision or control over the practice of medicine).

lation to these provider treatment decisions violates elementary principles of administrative law.

Under the APA, courts must invalidate regulations that are "arbitrary, capricious, [or] an abuse of discretion." 5 U.S.C. § 706(2)(A). This Court has consistently interpreted this provision to require, at a minimum, that administrative rules have a reasonable basis *in fact* and that the agency or department articulate a satisfactory explanation for its action, including a "rational connection between the facts found and the choice made." *See Motor Vehicle Manufacturers Assoc. of the United States, Inc.* v. *State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29, 43 (1983).[49] The Secretary's claim in her brief that, under the Final Regulation, she may investigate and regulate directly providers' decisions not to treat after parents consent fails to withstand scrutiny under both of these basic requirements.

First, and most importantly, the Secretary's argument is totally unsupported by any factual evidence that such alleged decisions are ever made by health care providers in the context of care for impaired newborns. Indeed, this "case" involves a wholly hypothetical situation that is on its face implausible: a health care provider would first have to communicate the treatment options to the infant's parents and then, after the parents selected a course of treatment, fail to provide it solely because of the infant's handicap. Such a failure to treat could subject the physician to tort liability and state disciplinary action under the licensing laws of all 50 states. *See* pp. 4-5, *supra*. Of course, HHS has not been able to cite even a single instance in which a provider has refused to provide a newborn infant medically indicated treatment which its parents have authorized—not in the preamble to the Final Regulation, not in any of her

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[49] This fundamental rule has often been emphasized by the Court. *See, e.g., Bowman Transportation, Inc.* v. *Arkansas-Best Freight System, Inc.*, 419 U.S. 281, 285-86 (1974); *Citizens to Preserve Overton Park, Inc.* v. *Volpe*, 401 U.S. 402, 416 (1971); *Burlington Truck Lines, Inc.* v. *United States*, 371 U.S. 156, 168 (1962).

lengthy regulatory pronouncements in this area, and not in her brief to this Court, which remarkably contains not one citation to *any* authority suggesting even the existence of such a case.[50]

Second, given its failure to cite a single case of what it purports to be regulating, HHS has *a fortiori* not been able in the preamble to the Final Regulation to establish any connection, much less a "rational connection," between the administrative record and its claimed authority to investigate providers' decisions in these circumstances. Indeed, there does not appear to be a single word in the Final Regulation, in its preamble, or in any of HHS's regulatory pronouncements even remotely suggesting that the purpose of HHS's presence in the delivery rooms and newborn nurseries was to review alleged provider decisions not to treat when parents of impaired newborns have authorized treatment.[51] In short, one looks in vain in the Secretary's regulatory pronouncements for any mention of, or justification for, the application of the Final Regulation to the hypothetical provider "non-treatment" decisions which are virtually the sole focus of her brief in this Court. The application of the Final Regulation to such decisions is demonstrably arbitrary and capricious and, therefore, unlawful, and this Court should so hold to prevent HHS from using it as a pretext to conduct intrusive, harmful investigations.[52]

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[50] *See* HHS Br. 15, 26 (HHS's paradigm example of refusal to treat is hypothetical only; no citation to specific case). *See also* 49 Fed. Reg. 1646-1649 (1984) (J.A. 95-106) (none of 49 cases reported by HHS involved this situation). In *University Hospital*, for example, the Court of Appeals noted that the hospital remained willing to perform corrective surgery on Baby Jane Doe if her parents would consent. (Pet. App. 39a). In the Baby Doe of Indiana case, parents refused to authorize treatment. HHS Br. 2.

[51] Moreover, nowhere in the administrative record did the Secretary ever discuss the state law duties of health care providers under state licensing statutes not to "abandon" patients; and nowhere did she explain why existing state law processes need to be short-circuited by her own direct involvement in the first instance.

[52] Moreover, the Secretary cannot, in her reply brief to this Court, make up for these obvious deficiencies. Administrative action may

2. *Section 504 Does Not Authorize Direct Federal Investigation And Regulation Of Such Provider Treatment Decisions.*

Application of the Final Regulation to physicians' decisions not to treat when parents have consented is also unlawful because it is plainly outside the scope of the Secretary's authority under Section 504.

a. The vast bulk of the Secretary's brief is spent deriving two propositions from the language and legislative history of Section 504. But neither proposition supports the Secretary's authority to investigate and determine the "reasonableness" of physicians' decisions in individual cases. First, HHS maintains that Section 504 applies generally to health services and mandates nondiscriminatory access to federally funded health services for otherwise qualified handicapped individuals.[53] This proposition, of course, is nothing more than a restatement of the general rule of Section 504 itself, and there have been a number of cases decided by the lower federal courts involving Section 504 and health services—none of which remotely supports the extreme construction of the statute urged here by the Secretary.[54]

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be upheld by a reviewing court, if at all, only on the same grounds articulated by the agency itself, and "appellate counsel's *post hoc* rationalizations for agency action" are impermissible. *Burlington Truck Lines, supra*, 371 U.S. at 168-169.

[53] The Secretary places principal reliance on the Senate report accompanying the 1974 amendment to Section 504 which listed "health services" along with employment, housing, transportation and education as areas to which Section 504 would apply. HHS Br. 35; S. Rep. No. 1297, 93rd Cong., 2d Sess. 39 (1974). *But cf., Alexander, supra*, 105 S. Ct. at 724 (the principal focus of Section 504 was not on health services but rather on employment, education and the elimination of physical barriers).

[54] *See, e.g., United States* v. *Cabrini Medical Center*, 639 F.2d 908 (2d Cir. 1981) (employment); *Southeastern Community College* v. *Davis*, 442 U.S. 397 (1979) (admission to nursing school); *Alexander* v. *Choate*, 105 S. Ct. 712 (1985) (reduction in health assistance). No case has approved the application of Section 504 to individual medical treatment decisions. Indeed, the Eighth

Second, HHS maintains that Section 504 specifically applies to "treatment" decisions involving otherwise qualified handicapped individuals. Although its brief is filled with enumerable references to bills, amendments and reports, HHS derives this proposition not from the legislative history of Section 504 but only from several examples —involving denial of medical treatment due to race, deafness, alcoholism and drug addiction—contained in the legislative histories of other statutes or in the preamble of the general Section 504 regulation promulgated in 1977.[55] But these examples, on their face, do not involve a federal determination first of an appropriate standard of medical care in an individual case and then a determination that the health care provider did not act in a "reasonable" or "*bona fide*" medical fashion. Instead, these examples all involve discriminatory general policies declaring *ineligible* for treatment broad types of individuals in which the minority status or handicapping condition—blacks denied surgery, deaf persons denied burn treatment and alcoholics denied cancer therapy—is on its face wholly unrelated to the condition requiring treatment.

Circuit recently dismissed a Section 504 claim alleging, in part, that a nursing home had discriminated against a resident by failing to provide adequate medical care, concluding that "[i]n substance, this is a medical malpractice case" not cognizable under Section 504. *Hoyt* v. *St. Mary's Rehabilitation Center*, 711 F.2d 864, 867 (8th Cir. 1983).

[55] *See* HHS Br. 11, 35-36 (example, drawn from Title VI, of black person denied medical treatment); *id.* 40 (example, drawn from 1977 general Section 504 regulations, of deaf person denied care by a burn treatment center); *id.* 37-39, 41-42 (example, drawn from 42 U.S.C. § 290dd-2(a), of alcoholic or drug addict denied care for unrelated medical condition). The only "health services" example drawn from the legislative history of Section 504 itself has nothing to do with treatment in individual cases after admission to a program. The Senate Report cites as the *only* example of the application of Section 504 to health services the denial of *admission* to a federally assisted nursing home solely on the basis of handicap. S. Rep. No. 1297, *supra*, at 38-39.

These examples are in sharp contrast to the Secretary's claim in this Court regarding her authority to investigate physicians' decisions involving impaired infants. The Secretary concedes that application of Section 504 to medical treatment decisions involving severely ill infants is "much more subtle and difficult" than more conventional applications, 49 Fed. Reg. 1636 (1984) (J.A. 61), and that, because of the inherent difficulty and complexity of determining appropriate medical care for impaired newborns, she is simply unable to develop even the most general standards for applying Section 504 in this swiftly changing area of medical practice, 49 Fed. Reg. 1632 (1984) (J.A. 46). Thus, the Secretary has announced that she can and will proceed only on a "case-by-case basis" to assess the standard of reasonable care with respect to the complex cases and then to determine whether providers in individual cases have made "reasonable" or *bona fide* medical treatment decisions as opposed to discriminatory decisions based solely on the handicap of an otherwise qualified infant. 49 Fed. Reg. 1632 (1984) (J.A. 46). *But cf., id.* 1634 (J.A. 52) (HHS refusal to commit to use medical consultants in all on-site investigations).

At the very least, as the Court of Appeals in *University Hospital* noted, the determination of whether a provider has "discriminated" in this sense against his infant patient would necessarily involve federally established "504 malpractice" standards, lengthy litigation, extraordinarily burdensome administrative costs, and no sure conclusion, especially in the highly complex and swiftly changing field of neonatology. (Pet. App. 30a-31a). As the only courts to address this issue have concluded, there is simply no support anywhere in the legislative history for this kind of direct establishment by HHS of a federal standard of care in individual cases and then a further determination whether providers have deviated from that standard of care in a way that is "discriminatory"

under Section 504.[56] Congress simply did not intend that HHS would determine in individual cases whether or not "medical treatment [was] contraindicated." HHS Br. 24.

b. The total lack of support in the "subjected to discrimination" language of Section 504 and in the legislative history of the Act for the Secretary's attempt to investigate and regulate directly the "reasonableness" of a physician's decision not to treat in an individual case after parental consent has been given should end the inquiry. But, even if there is some ambiguity on this point in the legislative history, the Secretary is barred from such an application of Section 504 because it would require a "substantial modification" in the provider's program prohibited under the rule of *Alexander* v. *Choate*.

If parents have consented to treatment, HHS can investigate only two types of situations. In the first, the physician does not himself treat but responds to the infant's condition by helping to obtain an alternative physician satisfactory to the parents.[57] In that situation the infant receives treatment, but HHS could nevertheless make a federal "504 malpractice" investigation and de-

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[56] *See University Hospital, supra*, 729 F.2d at 157-160 (Pet. App. 31a-38a); *American Academy of Pediatrics, supra*, 561 F. Supp. at 400 ("there is no customary standard of care" of impaired infants), 401 ("no congressional committee or member of the House or Senate ever even suggested that Section 504 would be used to monitor medical treatment of defective newborn infants . . ."). As noted, in its brief, HHS never addresses this fundamental holding in the Court of Appeals opinion. HHS Br. 26-28. *See* 49 Fed. Reg. 1630 (1984) (J.A. 38-39) (HHS recognition that individual cases will turn on experience and judgment). The hypothetical case cited repeatedly by HHS—a Down's Syndrome infant who is denied surgery to correct a blocked esophagus (HHS Br. 12-13, 15, 23, 26)—is, as HHS's *own emphasis* on case-by-case determinations indicates, a simplified example which is not likely to reflect medical realities. *See* pp. 5-7, *supra*; Brief for *Amici Curiae* American Academy of Pediatrics, *et al.* *See also* HHS Br. 5 n.2 (recognition of complicating factors).

[57] This could happen if the physician were faced with two emergencies simultaneously and could only treat one.

termination, even though no unlawful "abandonment" under state law has occurred. *See* p. 4, *supra*. The new federal substantive standard of medical care imposed upon health care providers in such a circumstance would involve an even more "fundamental modification" of a hospital's treatment program than the Secretary's attempt to enforce existing state reporting duties because federal standards of medical care are being established and enforced. Any HHS efforts to devise and enforce federal medical standards of care in this type of situation, where there has been no patient abandonment under state law, plainly violates the rule in *Alexander* v. *Choate*.

In the second situation, which is wholly implausible, the physician, after receiving parental consent, both refuses to treat a child who is severely impaired and declines in clear violation of state law to help parents secure a second physician to treat the infant. Obviously, this would be scandalous, but even in this hypothetical circumstance all of the rules of construction discussed in Part II undercut HHS's attempt to regulate before state authorities have acted. The federal intrusion laid on top of existing state enforcement mechanisms to deal with patient "abandonment" will significantly modify the hospital's program. *No* problem has been identified by the Secretary that warrants a federal role and therefore no deference is due to her extreme construction of the Act. Finally, the state would surely prosecute such a case and its prerogatives should not be interfered with solely on the basis of a tortured reading of Section 504 and without a clear statement from Congress that it wanted HHS involved in this fundamental issue of state regulation of medical practice.[58] Under applicable rules

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[58] There is little danger that, if such a scandalous case ever occurred, state authorities would not proceed promptly against the physician and any federal interest could be vindicated, as appropriate, after a final state law determination. There is danger, however, that if HHS is allowed to investigate this "type" of case before final state action it will, as it has in the past, direct its attention to cases where parents have not consented to treatment.

of construction, HHS simply cannot bootstrap itself into intensive care nurseries with broad Section 504 investigative powers based on so flimsy a hypothetical.

CONCLUSION

In *University Hospital*, the Court of Appeals concluded by noting (Pet. App. 40a-41a) that:

> it is congress, rather than an executive agency, that must weigh the competing interests at stake in this context in the first instance. Until congress has spoken, ... the type of investigation that has precipitated this lawsuit [is unlawful].

Following invalidation of HHS's Section 504 regulatory regime in this case, Congress weighed those interests and chose not to revive that regime. Instead, in the Child Abuse Amendments of 1984, note 20, *supra*, the Congress strengthened a state grant program and sought to help state child protective service agencies discharge their responsibilities in the context of severely impaired newborns.[59] A principal sponsor emphasized that: "This legislation does not itself authorize direct federal involvement in individual cases." *See* note 20, *supra* (letter of Sen. Hatch). In regulations implementing the new law, HHS has admitted that, in contrast to its Section 504 regulatory regime, Congress in the 1984 Child Abuse Amendments did not want a "new bureaucracy" created at the federal level to deal with treatment for impaired newborns; did not want creation of "federally prescribed medical standards for approved treatment of specific cases;" and did not want direct federal hotlines or other regulation of a hospital's internal affairs. 50 Fed. Reg. 14880, 14881, 14883-14884 (1985). HHS noted that the 1984 Amendments were "the product of an extraordinary effort" by Congres and medical,

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[59] *See* H.R. Conf. Rep. No. 1038, 98th Cong., 2d Sess. (1984) (federal grants to state child protective service agencies conditioned on incorporation of certain changes in state law and procedure).

"right-to-life" and disability groups "to forge a substantial consensus on an effective and workable program to assure" appropriate medical care for impaired newborns, concluding:

> It is clear that the legislation represented a careful balance between the need to establish effective protection of the rights of disabled infants and the need to avoid unreasonable governmental intervention into the practice of medicine and parental responsibilities. 50 Fed. Reg. 14879 (1985).

By contrast, HHS's 504 regulatory regime does not represent a careful balance by the Congress of the need to protect disabled infants and the need to avoid unreasonable governmental intervention into parental responsibilities and the practice of medicine. Indeed, the regulatory regime is far beyond anything remotely contemplated by the Congress and is clearly not authorized by Section 504. Accordingly, the judgment of the Court of Appeals should be affirmed.[60]

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[60] The judgment below (Pet. App. 50a-52a) enjoined HHS from (a) implementing the Final Regulation with respect to *individual treatment decisions* involving impaired newborns and (b) from otherwise investigating or regulating such decisions absent a specific regulation on the subject. Such decisions for impaired infants in individual cases are made only by parents and physicians. When parents do not consent to treatment for their child, Parts I and II, *supra*, have demonstrated that HHS has no authority to regulate parents' non-treatment decisions or physicians' duties under state law to report parental neglect. When parents do consent, Part III has demonstrated that HHS has no authority to regulate physicians' decisions. Accordingly, the judgment below should be affirmed and HHS should be enjoined from implementing the Final Regulation or otherwise regulating individual treatment decisions by parents or providers. As noted, the applicability of Section 504 to the enforcement practices of child protective service agencies is not presented by this case. *See* note 36, *supra*.

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November 4, 1985